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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,780	07/22/2002	Christopher John Secombes	ABLE-0021	9521

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LICATLA & TYRRELL P.C.  
66 E. MAIN STREET  
MARLTON, NJ 08053

EXAMINER

KELLY, ROBERT M

ART UNIT PAPER NUMBER

1632

DATE MAILED: 04/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

10/088,780

Applicant(s)

SECOMBES ET AL.

Examiner

Robert M. Kelly

Art Unit

1632

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 29 March 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☒ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: NONE.  
Claim(s) objected to: NONE.  
Claim(s) rejected: 1-7,9-18,21-26,28-40 and 42-54.  
Claim(s) withdrawn from consideration: NONE.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_  
13. ☐ Other: \_\_\_\_\_.

Continuation of 3. NOTE: With regard to the proposed claims, proposed independent claim 5 is limited to a method of passive immunization, which would require further search and examination consideration. Proposed claim 63 now no longer requires the secretion signal to be operably linked to the antibody-encoding sequence, which Applicant has not specifically pointed to where in the originally-filed specification or claims support is provided, and a preliminary review of such has provided none, hence this is new matter, as well as requiring further search and examination considerations. Applicant's proposed claim 65 now encompasses administration by injection, spray or gene gun of any formulation, which would require further search and examination considerations.

Continuation of 5. Applicant's reply has overcome the following rejection(s): Applicant's proposed amended claims would overcome the rejection under 35 USC 102 by the Chang patent.

Continuation of 11. does NOT place the application in condition for allowance because: Applicants proposed amended claims would overcome the rejections to the claims with respect to the 35 USC 112, second paragraph rejections. With respect to the enablement rejections, Applicant readdresses previous arguments and those are not considered persuasive for reasons of record. Applicant argues that the co-submitted Tjelle (2004) reference overcomes the enablement rejections, arguing that such provides proof of concept, but such is not considered persuasive, as Tjelle is limited to intramuscular injection of plasmid vectors, and the immunization is limited in time frame, thereby limiting the term of passive immunity, and thus this postfiling evidence is not considered enabling for the scope of the claims. Moreover, Tjelle recognizes that the methods "may" offer improvements over previous methods, not that it will offer such, for humans, and Applicant clearly contemplates the treatment of humans. Moreover, the co-submitted Perez paper says that the data is encouraging for future applications, but is careful to avoid stating that it is reasonably predictable, especially for the scope of Applicant's claims. The co-submitted Zon (1999) article appears to focus on Zebrafish and their use as a model of human disease, and does not even discuss immunizations. Moreover, Zon does not indicate that Zebrafish results will be reasonably predictable of results in humans, but only that the future appears bright for their use, due to the convenience of their study. Hence, Zon is not considered enabling for the full scope of Applicant's claims. Applicant's arguments concerning a written description rejection are not addressed, because the Examiner has not issued any written description rejection. Moreover, Applicant's arguments vis-à-vis possession do not apply to enablement, but only to written description. Applicant's only have an enablement rejection under the statute 35 USC 112, first paragraph. Applicant's argument with regard to the Duan reference is not considered persuasive because the argument contradicts itself: Applicant asserts that a reference cannot make obvious an invention if it would render the invention not useful for its intended purpose, but also demonstrates that the Duan reference actually acknowledges that it is an improvement over the prior art, which were for extracellular pathogens, as the prior rejection points out. Moreover, Applicant cites In re Gordon, but again Gordon does not say that the reference cannot make the invention obvious if it would render the invention not useful for its intended purpose, but that, if it would not render the claimed invention obvious to so-alter the prior art's invention, given a fair reading of the prior art reference as a whole (see Gordon @ ANALYSIS). Hence, Gordon actually supports the Examiner's position, because the Duan reference teaches an improvement over the prior art, thereby recognizing the prior art actually uses such signal sequences.



**DAVE TRONG NGUYEN**  
**PRIMARY EXAMINER**